UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

UNITED STATES OF AMERICA	)	
	)	
Plaintiff,	)	
	)	Cause No. _____
v.	)	
	)	
ELI LILLY AND COMPANY	)	
	)	
Defendant.	)	

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for permanent injunctive relief against Eli Lilly and Company ("Defendant"), and Defendant having appeared and having consented to the entry of this Consent Decree for Permanent Injunction ("Decree") without contest, without admitting the allegations of the Complaint, and before any testimony has been taken, and the United States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter herein, and has personal jurisdiction over Eli Lilly and Company pursuant to 21 U.S.C. § 332(a), and 28 U.S.C. §§ 1331, 1337, and 1345.

2. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

3. The Complaint for Permanent Injunction states a cause of action against Eli Lilly and Company under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301 et seq.

4. Eli Lilly and Company, and all of its subsidiaries, divisions, and controlled joint

ventures (hereafter collectively "Eli Lilly"), and each and all of their officers, directors, agents, employees, attorneys, and those persons in active concert and participation with them or any of them shall:

a. be permanently enjoined from violating the FDCA, 21 U.S.C. § 331(a), by directly or indirectly causing the introduction or delivery for introduction into interstate commerce of Evista, a human drug within the meaning of 21 U.S.C. § 321(g), that is misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that the labeling of the drug does not bear adequate directions for use in preventing or reducing the risk of breast cancer, reducing the risk of cardiovascular disease, or for any other unapproved use, unless and until it is authorized to do so by the United States Food and Drug Administration ("FDA") by the approval of a supplement to the New Drug Application for Evista;

b. be permanently enjoined from violating the FDCA, 21 U.S.C. § 331(k), by directly or indirectly causing Evista, a human drug within the meaning of 21 U.S.C. § 321(g), to be misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that the labeling of the drug does not bear adequate directions for use in preventing or reducing the risk of breast cancer, reducing the risk of cardiovascular disease, or for any other unapproved use, while such drug is held for sale after shipment of it or any of its components in interstate commerce, unless and until it is authorized to do so by the FDA by the approval of a supplement to the New Drug Application for Evista; and

c. be permanently enjoined from directly or indirectly promoting Evista for use in preventing or reducing the risk of breast cancer, reducing the risk of cardiovascular disease, or for any other unapproved use in a manner that violates the FDCA, 21 U.S.C. § 301 et seq., unless

and until it is authorized to do so by the FDA by the approval of a supplement to the New Drug Application for Evista.

d. Nothing in this Decree shall be construed to limit or expand the rights of Eli Lilly under the First Amendment of the Constitution.

5. This Decree shall be governed by the following definitions:

a. "Promotional and Product Services Related Functions for Evista" means selling, detailing, marketing, advertising, promotion, or branding Evista that is distributed in the United States, or the dissemination of information about Evista that is distributed in the United States.

b. "Covered Persons" includes:

i. all employees of Eli Lilly engaged in or directly responsible for Promotional and Product Services Related Functions for Evista, and those members of the Legal, Regulatory, Medical, Medical Information Services, Human Resources, and Sales and Marketing Training functions that support these individuals;

ii. all contractors, subcontractors, agents, and other persons engaged in or directly responsible for Promotional and Product Services Related Functions for Evista on behalf of Eli Lilly;

iii. all employees of any contract sales force or other entity contracted by Eli Lilly engaged in or directly responsible for Promotional and Product Services Related Functions for Evista on behalf of Eli Lilly;

iv. Notwithstanding the above, the term "Covered Person" does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per calendar year, except that any such

person shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year. The term "Covered Persons" does not include any contractors, subcontractors, agents, and other persons retained to provide consulting or business advice to Eli Lilly and who are not engaged in or directly responsible for any Promotional and Product Services Related Functions for Evista on behalf of Eli Lilly. Also specifically excluded from this definition of "Covered Persons" are the personnel of advertising agencies hired by Eli Lilly to develop advertising for Evista, and personnel of entities with which Eli Lilly has agreements to co-promote Evista.

v. Eli Lilly shall, however, in good faith seek to obtain assurances that persons identified in Paragraph 5.b(iv) who are not a "Covered Person" have received appropriate training on proper promotional activities.

c. "Evista" is the name of the pharmaceutical drug raloxifene hydrochloride produced and distributed by Eli Lilly.

d. "Government" means the FDA and Department of Justice, Office of Consumer Litigation.

e. "FDA Requirements" means the FDCA and applicable regulations (excluding regulations governing current good manufacturing practices) of the FDA governing the distribution, sale, detailing, marketing, advertising, promotion, branding, or disseminating of information about Evista in the United States.

f. "Federal Health Care Program Requirements" means the statutes and regulations of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) governing the distribution, sale, detailing, marketing, advertising, promotion,

branding, or disseminating of information about Evista in the United States.

g. The Effective Date shall be the date on which this Decree is entered by the Court.

h. The Implementation Date shall be one hundred and twenty (120) days after the Effective Date.

COMPLIANCE PROGRAM

6. Eli Lilly currently has a Compliance Program. Eli Lilly shall continue to maintain a Compliance Program to promote and require compliance by its Board of Directors, officers, executives, managers, employees, contractors, subcontractors and agents with this Decree, FDA Requirements, and Federal Health Care Program Requirements. Eli Lilly shall abide by the provisions of Paragraph 6 of this Decree (the "Compliance Program") for a period of five (5) years from the Effective Date. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period." To the extent not already part of Eli Lilly's current Compliance Program, Eli Lilly shall establish or maintain a Compliance Program that includes the following elements:

a. **Chief Compliance Officer.** Eli Lilly currently has a Chief Compliance Officer with responsibility for administering Eli Lilly's Compliance Program. Eli Lilly shall continue to employ an individual to serve as its Chief Compliance Officer during the term of this Decree. After the Effective Date, the Chief Compliance Officer shall be responsible for directing and implementing systems, processes, policies, and procedures to promote and require compliance with this Decree, FDA Requirements, and Federal Health Care Program Requirements. The Chief Compliance Officer is, and shall continue to be, a member of senior executive management of Eli Lilly. The Chief Compliance Officer shall make periodic (at least semi-

annual) written reports regarding compliance with this Decree directly to the Board of Directors (or its designated subcommittee), and shall be authorized to report in writing on compliance with this Decree to the Board of Directors at any time. The Chief Compliance Officer shall be authorized to request that the Board of Directors (or its designated subcommittee) retain outside counsel in appropriate circumstances. The Chief Compliance Officer shall continue to be responsible for monitoring Eli Lilly's day-to-day compliance activities and shall be responsible for all obligations created under this Decree. Eli Lilly shall report to the Government, in writing, any changes in the identity of or any material changes in the position description of the Chief Compliance Officer, or any material actions or changes that could affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this Decree, within fifteen (15) business days after such a change.

b. **Compliance Committee.** Eli Lilly currently has and shall continue to maintain a Compliance Committee during the term of this Decree. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to promote and require compliance with this Decree (e.g., senior executives of relevant departments, such as Audit, Regulatory Affairs, Sales, Sales Compliance, Marketing, Marketing Compliance, and Human Resources). The Chief Compliance Officer shall continue to chair the Compliance Committee, which shall support the Chief Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Eli Lilly's risk areas and shall oversee monitoring of internal and external compliance audits). Eli Lilly shall report to the Government, in writing, any material changes in the composition of the Compliance Committee, or any material actions or changes that could affect the Compliance Committee's ability to perform the

duties necessary to meet the obligations in this Decree, within fifteen (15) business days after such a change.

c. **Written Standards.**

i. Red Book.

(1) Prior to the Effective Date, Eli Lilly implemented a written Code of Conduct (known as the Red Book). Eli Lilly has distributed the Red Book to all Covered Persons and required all Covered Persons to complete training on the Red Book. Within ninety (90) days after the Effective Date, each Covered Person shall certify, electronically or in writing, that he or she has received, read, understands and shall abide by the Red Book.

(2) Eli Lilly shall make the promotion of, and adherence to, the Red Book an element in evaluating the performance of all Covered Persons. The Red Book shall embody Eli Lilly's commitment to comply with this Decree, FDA Requirements, and Federal Health Care Program Requirements.

(3) New Covered Persons shall receive the Red Book and shall, within sixty (60) days after becoming a Covered Person or within one hundred and twenty (120) days after the Effective Date, whichever is later, certify, electronically or in writing, that he or she has received, read, understands and shall abide by the Red Book. For purposes of this Paragraph, Eli Lilly may use such electronic methods of distribution and/or certification as it deems appropriate, provided that a written or electronic record is maintained of such distributions and certifications.

(4) Eli Lilly shall at least annually review the Red Book to determine whether revisions are appropriate and shall make any necessary revisions based on such review.

Any materially revised Red Book shall be distributed within sixty (60) days after any such revisions are finalized. Each Covered Person shall certify, electronically or in writing, that he or she has received, read, understands, and shall abide by the revised Red Book within forty-five (45) days after the distribution of the revised Red Book.

ii. Policies and Procedures.

(1) Eli Lilly either has implemented or will implement within ninety (90) days after the Effective Date written Policies and Procedures ("Policies and Procedures") regarding Eli Lilly's compliance with this Decree, FDA Requirements, and Federal Health Care Program Requirements. Within one hundred and twenty (120) days after the Effective Date, each Covered Person shall certify, electronically or in writing, that he or she has received, read, understands and shall abide by Eli Lilly's Policies and Procedures.

(2) Eli Lilly shall make the promotion of, and adherence to, Eli Lilly's Policies and Procedures an element in evaluating the performance of all Covered Persons. At a minimum, these Policies and Procedures, referred to as Good Promotional Practices (GPPs), Marketing Compliance Promotional Practices (CPPs), or other policies and procedures as may be appropriate, shall address, and shall continue to address:

(a) the subjects addressed in the Red Book;

(b) Eli Lilly's commitment to comply with this Decree, FDA Requirements, and Federal Health Care Program Requirements;

(c) marketing, promotion, detailing, advertising and selling Evista in compliance with this Decree, FDA Requirements, and Federal Health Care Program Requirements;

(d) the manner in which Medical Information Services receives and responds to requests for information about off-label uses of Evista; the form and content of the information disseminated by Medical Information Services in response to such requests; and the internal review process for the information disseminated;

(e) that speaker programs relating to the marketing or promotion of Evista, or similar or related events, comply with this Decree, FDA Requirements, and Federal Health Care Program Requirements;

(f) that meetings to obtain healthcare professional input or feedback, speaker training meetings, Advisors and Advisory Board meetings, Consultant Task Force meetings, Market Research meetings, and preceptor meetings, relating to Evista, or similar or related events, comply with this Decree, FDA Requirements, and Federal Health Care Program Requirements. The Policies and Procedures shall provide that the consultant or contractor arrangements and related and similar events are used for legitimate and lawful purposes in compliance with this Decree, FDA Requirements, and Federal Health Care Program Requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;

(g) that sponsorship or funding of continuing medical education ("CME") programs comply with this Decree, FDA Requirements, and Federal Health Care Program Requirements. The Policies and Procedures shall require the disclosure to attendees of the CME of Eli Lilly's financial support of the CME program and any financial relationship with faculty and speakers at such CME program; shall require that the CME program have an educational focus; and shall require that the content of the CME program be

independent of Eli Lilly;

(h) that sponsorship or funding of grants (excluding grants for Phase I, Phase II or Phase III studies) comply with this Decree, FDA Requirements, and Federal Health Care Program Requirements;

(i) that sponsorship or funding of post-marketing research and related activities or authorship of articles or other publications, comply with this Decree, FDA Requirements, and Federal Health Care Program Requirements;

(j) the possible consequences, including citation for contempt and criminal prosecution, for both Eli Lilly and Covered Persons, of failing to comply with this Decree, FDA Requirements, and Federal Health Care Program Requirements, and the failure to report such noncompliance to the Chief Compliance Officer or her designee accurately and completely;

(k) the requirement that all of Eli Lilly's Covered Persons shall promptly report to the Chief Compliance Officer suspected violations of this Decree, FDA Requirements, and Federal Health Care Program Requirements;

(l) disciplinary sanctions in place for violations of this Decree, FDA Requirements, and Federal Health Care Program Requirements; and

(m) the right of all individuals to use the Disclosure Program described in Paragraph 6.f, and Eli Lilly's commitment not to retaliate against such individuals.

(3) New Covered Persons shall receive the Policies and Procedures and shall, within sixty (60) days after becoming a Covered Person or within ninety (90) days after the Effective Date, whichever is later, certify, electronically or in writing, that he or she has

received, read, understands and shall abide by the Policies and Procedures. For purposes of this Paragraph, Eli Lilly may use such electronic methods of distribution and/or certification as it deems appropriate, provided that a written or electronic record is maintained of such distributions and certifications.

(4) At least annually (and more frequently, if appropriate), Eli Lilly shall review the Policies and Procedures to determine whether revisions are appropriate and shall make any necessary revisions based on such review. Any materially revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures within sixty (60) days after any such revisions are finalized. Each such Covered Person shall certify, electronically or in writing, that he or she has received, read, understands, and shall abide by the revised Policies and Procedures within thirty (30) days after the distribution of the revised Policies and Procedures.

(5) To the extent that changes in the laws regarding the FDA Requirements and/or the Federal Health Care Program Requirements require Eli Lilly to materially revise its Policies and Procedures, Eli Lilly will have ninety (90) days to revise its Polices and Procedures. Any materially revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures within forty-five (45) days after any such revisions are finalized. Each such Covered Person shall certify, electronically or in writing, that he or she has received, read, understands, and shall abide by the revised Policies and Procedures within forty-five (45) days after the distribution of the revised Policies and Procedures.

d. **Training.** The training required under this Paragraph shall be provided by

supervisory employees, knowledgeable staff, Eli Lilly trainers or outside consultant trainers. Persons providing the training shall be knowledgeable about the subject areas of their training. Eli Lilly may provide the training required under this Decree through appropriate computer-based approaches. In that event, all applicable references to "hours" in this Paragraph shall mean "normative hours" as that term is used in the computer-based training industry. If Eli Lilly chooses to provide computer-based training, it shall also make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the Covered Persons who are receiving such training. Eli Lilly shall provide training, as outlined below, to all Covered Persons within one hundred and twenty (120) days after the Effective Date. The training shall last for at least two (2) hours. Thereafter, at least annually, all Covered Persons shall receive at least two (2) additional hours of training, as outlined below. The training shall be tailored to the Covered Persons' job responsibilities and shall include a discussion of the topics outlined in Paragraph 6.d(i)(1)-(4).

i. The training shall include a discussion of:

(1) Eli Lilly's obligations under this Decree;

(2) Each Covered Person's obligations under this Decree, FDA Requirements, and Federal Health Care Program Requirements;

(3) the civil and criminal legal sanctions for violations of this Decree, FDA Requirements, and Federal Health Care Program Requirements; and

(4) examples of improperly selling, detailing, marketing, advertising, promoting Evista, and improperly disseminating information about off-label use of Evista.

ii. New Covered Persons, including employees returning from a leave of

absence, shall receive the training outlined above within forty-five (45) days after beginning or recommencing their employment or becoming Covered Persons or within sixty (60) days after the Effective Date, whichever is later. An Eli Lilly employee who has successfully completed the training shall supervise a new Covered Person's work, to the extent the new Covered Person is engaged in Promotional and Product Services Related Functions for Evista, until such time as the new Covered Person successfully completes the applicable training.

iii. At least annually, Eli Lilly shall review the training, and, where appropriate, update the training to reflect changes in FDA Requirements, Federal Health Care Program Requirements, and any relevant issues discovered during the Reviews (as set forth in Paragraph 6.e).

iv. Each Covered Person who is required to attend training shall certify, electronically or in writing, that he or she has received and understands the required training and shall abide by the legal requirements covered in the training. Eli Lilly shall maintain records specifying the training provided to each Covered Person, the date(s) provided, and the Covered Person's certification. The Chief Compliance Officer (or designee) shall retain the certifications and the training tracking information. This information shall be made available to the Government, upon request.

e. **Independent Review Organizations or Corporate Audit Services.** Within ninety (90) days after the Effective Date, Eli Lilly shall retain an independent entity (or entities) (hereinafter, "Independent Review Organization" or "IRO") to conduct reviews to assist Eli Lilly in assessing and evaluating Eli Lilly's systems, processes, policies, and procedures relating to the Promotional and Product Services Related Functions for Evista, and Eli Lilly's compliance with

this Decree. Each IRO shall have expertise in FDA requirements related to the sale and promotion of pharmaceutical products, as may be appropriate to the specific Engagement for which it is retained. Each IRO shall be without significant financial ties (other than the IRO agreement or indirect ownership of Eli Lilly, e.g., through diversified mutual funds or pension funds) to Eli Lilly. Each IRO shall be without significant personal ties to an Officer of Eli Lilly or a Covered Person. Except as provided for in Paragraph 6.e(ii)(1), Eli Lilly shall retain an IRO to perform two types of Engagements: a Systems Engagement and a Transactions Engagement. For purposes of the Engagements, the Engagement Period for the First Reporting Period shall be the period from the Implementation Date through the first anniversary of the Effective Date. The Engagement Period for the Second Reporting Period through the Fifth Reporting Period shall be each respective corresponding Reporting Period (*i.e.*, the period from the relevant anniversary of the Effective Date through the subsequent anniversary). Eli Lilly may engage, at its discretion, a single IRO to perform both the Systems Engagement and the Transactions Engagement, provided that the IRO has the expertise and capabilities to perform both.

i. The Systems Engagement, as described in Attachment A, shall be performed for the periods covering the First and Fourth Reporting Periods, provided there are no material changes in Eli Lilly's systems, processes, policies, or procedures relating to the selling, detailing, marketing, advertising, promotion, and medical information services for Evista. If Eli Lilly materially changes such systems, processes, policies, or procedures, the IRO shall perform a Systems Engagement for the Reporting Period in which such changes were made in addition to conducting the Systems Engagement for the First and Fourth Reporting Periods.

ii. The Transactions Engagement, as described in Attachment A, shall be performed on an annual basis for the First through Fifth Reporting Periods.

(1) After an IRO performs the Transaction Engagement for the first three Reporting Periods of this Decree, Eli Lilly may, at its option, request the Government to permit the Transactions Engagement to be conducted by Eli Lilly's Corporate Audit Services ("CAS") subject to verification by an IRO. The Government retains sole discretion over whether to permit the Transaction Engagement to be conducted by the CAS. In making its decision, the Government will consider, among other factors, the results of the Transaction Engagement for the first three Reporting Periods and Eli Lilly's demonstrated capabilities to perform the Transaction Engagement internally. If the Government denies Eli Lilly's request to shift the Engagement responsibilities to CAS, Eli Lilly shall engage an IRO to perform the remaining Transaction Engagements.

(2) Any Transactions Engagement conducted by CAS shall be subject to verification by an IRO, as described in Attachment A.

iii. For each Engagement, the IRO or CAS shall prepare a written report (or reports). Information to be included in the report(s) is detailed in Attachment A. The written report (or reports) shall be submitted pursuant to Paragraph 6.k(i)(5).

iv. For each verification by an IRO, the IRO shall prepare a written report (or reports). Information to be included in the report(s) is detailed in Attachment A. The written report (or reports) shall be submitted pursuant to Paragraph 6.k(i)(5).

v. The IRO, CAS, and Eli Lilly shall retain and make available to the Government, upon request, all work papers, supporting documentation, correspondence, and

draft reports (those exchanged within the IRO, and between the IRO and Eli Lilly) related to the Engagements for a period of six years after the Effective Date.

vi. In the event the Government has reason to believe that (a) any of Eli Lilly's CAS or IRO Engagements fails to conform to the requirements of this Decree, (b) the findings or reports from these Engagements are inaccurate, or (c) that Eli Lilly is not complying with this Decree, FDA Requirements, or Federal Health Care Program Requirements, the Government may, at its sole discretion, conduct its own review(s) to determine whether the Engagement(s) complied with the requirements of this Decree, and/or the findings or Engagement review results are inaccurate, incomplete, or untruthful ("Validation Review"). Eli Lilly shall pay for the cost of any such Validation Review(s) performed by the Government or any of its designated agents, pursuant to the rates specified in Paragraph 18, so long as the notification in Paragraph 6.e(vii) is initiated within two years after the written report on the respective Engagement is received by the Government.

vii. Prior to initiating a Validation Review, the Government shall notify Eli Lilly of its intent to do so and provide a written explanation of why the Government believes such a review is necessary. To resolve any concerns raised by the Government, Eli Lilly may request a meeting with the Government to discuss the results of any Engagement submissions or findings; present any additional or relevant information to clarify the results of the Engagement or to correct any inaccuracies; or propose alternatives to the proposed Validation Review. Eli Lilly shall provide any additional information as may be requested by the Government under this Paragraph in an expedited manner. The Government will attempt in good faith to resolve any Engagement review issue with Eli Lilly prior to conducting a Validation Review. However, the

final determination as to whether to proceed with a Validation Review shall be made at the sole discretion of the Government.

viii. Within one hundred and twenty (120) days after the Effective Date, Eli Lilly shall submit a written notification to the Government containing the following information regarding the IRO:

(1) the identity, address, and phone number;

(2) a copy of all contracts and agreements between Eli Lilly and the IRO;

(3) the proposed start and completion dates of the Engagements identified in Paragraph 6.e; and

(4) a certification from Eli Lilly's Chief Compliance Officer and the IRO regarding the IRO's professional independence and/or objectivity with respect to Eli Lilly. If Eli Lilly undertakes good faith efforts to secure an independence certification from the IRO(s), the failure to do so shall not constitute a breach of this Decree by Eli Lilly and shall not constitute a basis upon which the Government may impose Stipulated Penalties; however, such a failure shall constitute a basis upon which the Government may initiate a Validation Review.

ix. If at any time Eli Lilly retains a new IRO, Eli Lilly shall, within thirty (30) days of retaining the new IRO, submit a written notification to the Government containing the information required in Paragraph 6.e(viii)(1)-(4).

f. **Disclosure Program.** Eli Lilly presently has a Disclosure Program designed to facilitate communication relating to compliance with FDA Requirements, Federal Health Care Program Requirements, and Eli Lilly's policies. During the term of this Decree, Eli Lilly shall

maintain a Disclosure Program, which includes a process to enable individuals to disclose to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any issues or questions associated with compliance or failure to comply with this Decree, and Eli Lilly's policies, conduct, practices, or procedures with respect to FDA Requirements or Federal Health Care Program Requirements believed by the individual to be a potential violation of criminal, civil, or administrative law, or a violation of this Decree. During the term of this Decree, Eli Lilly shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to Covered Persons or by posting the information in prominent common areas).

i. The Disclosure Program shall continue to emphasize a clear, non-retribution, non-retaliation policy, and shall continue to include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual(s). The Chief Compliance Officer (or designee) shall make a preliminary, good faith, due-diligence inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably:

(1) permits a determination of the appropriateness of the alleged improper practice; and

(2) provides an opportunity for taking corrective action,

the Chief Compliance Officer (or designee) shall conduct a review of the allegations set forth in

the disclosure and ensure that proper follow-up is conducted.

ii. The Chief Compliance Officer (or designee) shall continue to maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and all corrective action taken in response to the review(s).

g. **Reportable Events.** For purposes of this Decree, a "Reportable Event" means anything that involves a matter occurring after November 16, 2004, brought to the attention of Eli Lilly's Chief Compliance Officer, a member of Compliance Committee, or any other member of senior executive management at Eli Lilly, that a reasonable person would consider a possible violation of this Decree, FDA Requirements, or Federal Health Care Program Requirements. A Reportable Event may be the result of an isolated event or a series of occurrences. If the Chief Compliance Officer determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, the Chief Compliance Officer shall notify the Government, in writing, within twenty (20) days after making the determination that the Reportable Event exists. The written report to the Government shall include the following information:

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal authorities implicated;

ii. a description of Eli Lilly's actions taken to investigate and correct the Reportable Event;

iii. any further steps Eli Lilly plans to take to address the Reportable Event and prevent it from recurring; and

iv. a copy of the Disclosure Log entry described in Paragraph 6.f(ii), if any, related to the Reportable Event.

h. **Notification of Detailing Activity.** Each Reporting Period, Eli Lilly shall obtain commercially available non-Eli Lilly records reflecting the purported content and subject matter of detailing interactions between sales representatives and health care professionals for Evista. Eli Lilly shall randomly select one week within each of the first three quarters of the Reporting Period. Eli Lilly shall obtain all such records reflecting the purported content and subject matter of Evista detailing sessions that occurred during the identified week in all regions across the United States. Eli Lilly shall review the records obtained and shall identify any instances in which the records appear to indicate that Covered Persons may have discussed and/or disseminated information about off-label uses of Evista. Eli Lilly shall make findings based on its review ("Off-Label Findings") and shall take any corrective action it deems necessary. If necessary for purposes of its review, Eli Lilly shall endeavor to collect additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report, Eli Lilly shall provide the Government with copies of such records of the detailing interactions, a copy of each of Eli Lilly's Off-Label Findings, and a description of the action(s), if any, Eli Lilly took in response to the Off-Label Findings. This Paragraph is subject to the availability of the records described above, and Eli Lilly shall make good faith efforts to obtain such records. If Eli Lilly is unable to obtain such records, Eli Lilly shall notify the Government and shall describe to the Government the efforts undertaken to obtain the records.

i. **Notification of Usage.** At least ninety (90) days prior to the beginning of the Second Reporting Period and each Reporting Period thereafter, Eli Lilly shall provide to the

Government detailed information (by International Classification of Diseases code) about the estimated relative usage of Evista during the current Reporting Period. Such information shall be based on usage statistics conveyed to Eli Lilly by an independent third party (e.g., IMS Health, Verispan, LLC, or any other independent third party) with experience in measuring sales of pharmaceutical drugs in the United States. Eli Lilly and the Government shall agree on the independent third party before Eli Lilly acquires the usage information.

j. **Notification of Message Recall Data.** For each Reporting Period, Eli Lilly shall submit to the Government all market research, if any, conducted by or for the Evista Brand Team or Eli Lilly Market Research to measure physician recall of the marketing messages by Eli Lilly sales representatives for Evista. Along with the underlying data, Eli Lilly shall submit any summary, report, or presentation that accompany or describe the data.

k. **Annual Reports.** Eli Lilly shall submit to the Government annually a written report with respect to the status of, and findings regarding, Eli Lilly's compliance activities related to this Decree for each Reporting Period.

i. Each Annual Report shall include:

(1) a description of any change in the identity, position description or other non-compliance job responsibilities of the Chief Compliance Officer and any change in the composition of the Compliance Committee;

(2) for the First Reporting Period, a copy of the Red Book; for subsequent Reporting Periods, a description of any change(s) to the Red Book, a copy of the change(s), and the reasons for such change(s);

(3) for the First Reporting Period, a copy of the Policies and

Procedures required by Paragraph 6.c(ii); for subsequent Reporting Periods, a description of any change(s) to the Policies and Procedures, a copy of the change(s), and the reasons for such change(s);

(4) the following information regarding each type of training required by Paragraph 6.d:

(a) a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

(b) the number of Covered Persons required to be trained, percentage of Covered Persons actually trained, and an explanation of any exceptions; and

(c) copy of all training materials.

(5) a complete copy of all reports prepared pursuant to Paragraph 6.e;

(6) Eli Lilly's response and corrective action plan(s) related to any issue raised by the reports prepared pursuant to Paragraph 6.e;

(7) a certification from the IRO(s) regarding its professional independence and/or objectivity with respect to Eli Lilly;

(8) a summary of each disclosure in the disclosure log required by Paragraph 6.f:

(9) a summary of each Reportable Event, as defined in Paragraph 6.g identified during the Reporting Period, and the status of any corrective and preventative action relating to each such Reportable Event;

(10) as required by Paragraph 6.h, copies of the third party records, a copy of each of Eli Lilly's Off-Label Findings, and a description of the action(s), if any, Eli Lilly

took in response to each Off-Label Finding;

(11) the information required by Paragraph 6.i;

(12) the documents required by Paragraph 6.j;

(13) the number of new Covered Persons required to complete the certification required by Paragraph 11, the percentage of new Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to the Government, upon request).

ii. The first Annual Report shall be received by the Government no later than sixty (60) days after the end of the First Reporting Period. Subsequent Annual Reports shall be received by the Government no later than the anniversary date of the date the first Annual Report is due.

iii. The Annual Reports shall include a certification by the Chief Compliance Officer that:

(1) Eli Lilly's Red Book, Policies and Procedures (as referenced in Paragraph 6.c(ii)), and all materials relating to Evista requiring Blue Jacket approval have been reviewed by legal counsel or regulatory affairs for compliance with this Decree and FDA Requirements;

(2) all materials relating to Evista requiring Pink Sheet approval have been reviewed by legal counsel or regulatory affairs for compliance with this Decree and FDA Requirements;

(3) except as otherwise described in the applicable Annual Report, that Eli Lilly is in compliance with this Decree; and

(4) the Chief Compliance Officer has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes that the information in the Annual Report is accurate and truthful.

iv. Eli Lilly shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Eli Lilly shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

7. Eli Lilly and the Government hereby agree that failure to comply with certain obligations as set forth in this Decree may lead the Government to seek the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions:

a. A Stipulated Penalty of up to $50,000 for each false certification submitted by or on behalf of Eli Lilly as part of its IRO Selection Notification, Annual Report, additional documentation to a report (as requested by the Government), or other documentation required by this Decree;

b. A Stipulated Penalty of up to $50,000 for each violation of Paragraph 4 of this Decree;

c. A Stipulated Penalty up to $10,000 for each day Eli Lilly fails to comply fully and adequately with any other obligation of this Decree. The Government shall provide notice to Eli Lilly, stating the specific grounds for its determination that Eli Lilly has failed to comply fully or

adequately with this Decree obligation(s) at issue and steps Eli Lilly shall take to comply with this Decree. A Stipulated Penalty as described in this Subparagraph shall begin to accrue ten (10) business days after Eli Lilly receives this notice from the Government of the failure to comply (the "due date"). A Stipulated Penalty as described in this Subparagraph shall not be demanded for any violation for which the Government has sought a Stipulated Penalty under Paragraphs 7.a or 7.b;

d. Eli Lilly may, in advance of the due date as defined in Paragraph 7.c, submit a timely written request for an extension of time to perform any act or file any notification or report required by this Decree. Notwithstanding any other provision in Paragraph 7, if the Government grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until the day after Eli Lilly fails to meet the revised deadline approved by the Government. Notwithstanding any other provision in Paragraph 7, if the Government denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three (3) business days after Eli Lilly receives the Government's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by the Government at least five (5) business days prior to the date by which any act to be performed or any notification or report is due to be filed; and

e. If Eli Lilly disagrees with the Government's determination with respect to a Stipulated Penalty, it may, within ten (10) business days of receipt of the Government's determination, appeal the Government's determination to this Court. Eli Lilly's failure to appeal

the Government's determination to this Court within the time frames required by this Decree shall constitute a waiver of the right to seek judicial review of the Government's determination, and Eli Lilly shall pay the Stipulated Penalties within ten (10) business days. In the event that Eli Lilly files a timely appeal to this Court, the Government shall provide the written record before FDA at the time the decision was made, whereupon the Court will decide the matter pursuant to the standard set forth in Paragraph 29 of this Decree.

f. If Eli Lilly agrees with the Government's determination with respect to a Stipulated Penalty, it shall, within ten (10) business days of receipt of the Government's determination, pay the Stipulated Penalty.

DISGORGEMENT

8. In full monetary settlement of the allegations set forth in the Complaint in this matter, Eli Lilly agrees to pay equitable disgorgement to the United States Treasury the total amount of twenty-four million dollars ($24,000,000) no later than ten (10) days after the entry of this Decree as directed by the Government.

9. The parties acknowledge that the payment described in Paragraph 8 is not a fine, penalty or payment in lieu thereof.

DISTRIBUTION OF DECREE

10. Within thirty (30) days after the Effective Date, Eli Lilly shall provide a copy of this Decree to each member of its Board of Directors and all Covered Persons. Each recipient of this Decree shall certify, electronically or in writing, that he or she has received, read, understands, and shall abide by this Decree. Within forty-five (45) days after the Effective Date, the Chief Compliance Officer shall advise the Government in writing that each member of Eli

Lilly's Board of Directors and each Covered Persons has certified, electronically or in writing, that he or she has received, read, understands, and shall abide by this Decree.

11. New Covered Persons shall receive this Decree and shall complete the required certification within thirty (30) days after becoming a Covered Person or within sixty (60) days after the Effective Date, whichever is later. Each new Covered Person shall certify, electronically or in writing, that he or she has received, read, understands, and shall abide by this Decree.

12. Eli Lilly shall post a copy of this Decree on its Intranet site within ten (10) business days of the Effective Date.

GENERAL PROVISIONS

13. The Chief Compliance Officer (or designee) shall retain all certifications required by this Decree. These certifications shall be made available to the Government, upon request.

14. If, at any time after entry of this Decree, the Government determines that Eli Lilly has failed to comply with any provision of this Decree, or that any corrective actions are necessary to achieve compliance with this Decree (the "Government's determination"), the Government may, as and when it deems necessary, order Eli Lilly in writing to take corrective action(s) as the Government, in its discretion, deems necessary to bring Eli Lilly into compliance with this Decree. All costs of such corrective action(s) shall be borne by Eli Lilly. The costs of FDA inspections, travel time, and subsistence expenses to implement and monitor the remedies set forth in this Paragraph shall be borne by Eli Lilly at the rates specified in Paragraph 21. This provision shall be separate and apart from, and in addition to, all other remedies available to the Government.

a. If Eli Lilly agrees with the Government's determination, Eli Lilly shall notify the Government in writing within ten (10) business days of receipt of the Government's determination that Eli Lilly is undertaking or has undertaken the corrective action(s), in which event Eli Lilly also shall describe the specific action(s) taken or proposed to be taken and a proposed schedule for completing the action.

b. If Eli Lilly disagrees with the Government's determination, Eli Lilly shall seek administrative review thereof. In seeking administrative review, Eli Lilly shall respond in writing within ten (10) business days of receipt of the Government's determination, explaining the basis for its disagreement; in doing so, Eli Lilly may also propose specific alternative actions and specific time frames for achieving the Government's corrective action.

c. If Eli Lilly seeks administrative review, the Government will inform Eli Lilly of the results of the administrative review and the Government's final determination (the "Government's final determination").

i. If Eli Lilly agrees with the Government's final determination, Eli Lilly shall notify the Government in writing within ten (10) business days of receipt of the Government's final determination that Eli Lilly is undertaking or has undertaken the corrective action(s), in which event Eli Lilly also shall describe the specific action(s) taken or proposed to be taken and a proposed schedule for completing the action.

ii. If Eli Lilly disagrees with the Government's final determination, it may, within ten (10) business days of receipt of the Government's final determination, appeal the Government's final determination to this Court. However, if Eli Lilly appeals the Government's final determination to this Court, Eli Lilly shall diligently and in good faith implement the

Government's final determination and corrective action(s), unless and until the Government or the Court issues an order to the contrary.

e. Eli Lilly's failure to appeal the Government's final determination to this Court within the time frames required by this Decree shall constitute a waiver of the right to seek judicial review of the Government's final determination. In the event that Eli Lilly files a timely appeal to this Court, the Government shall provide the written record before FDA at the time the decision was made, whereupon the Court will decide the matter pursuant to the standard set forth in Paragraph 29 of this Decree.

15. Any corrective action described in Paragraph 14 shall continue until Eli Lilly receives written notification from the Government that Eli Lilly appears to be in compliance with this Decree, or a court order is issued pursuant to Paragraph 14.

16. In addition to any other rights the Government may have by statute, regulation, or contract, the Government or its duly authorized representative(s) may make such inspections as the Government deems necessary and without notice, including but not limited to, inspections and on-site reviews of any of Eli Lilly's locations or offices for the purpose of verifying and evaluating Eli Lilly's compliance with this Decree. The Government may examine and copy Eli Lilly's books, records, files, papers, promotional materials, and other documents and supporting materials (to the extent such items are not protected under appropriately asserted legal privilege). Eli Lilly agrees to promptly provide such material to the Government at a central location. Furthermore, to ensure compliance with this Decree, the Government or its duly authorized representative(s) may, as agreed to by the Government and the employee(s), interview any of Eli Lilly's employees, contractors, or agents at the individual's place of business during normal

business hours or at such other place and time as may be mutually agreed upon between the individual and the Government. The inspections described in this Decree shall be permitted upon presentation of a copy of this Decree and appropriate credentials.

17. Eli Lilly shall maintain for inspection and copying all documents and records relating to Promotional and Product Services Related Functions for Evista, and compliance with this Decree for five (5) years (or longer, if otherwise required by law) from the Effective Date.

18. Eli Lilly shall pay the non-legal costs of FDA's supervision, inspection, analysis, review, and examination conducted pursuant to this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: $73.55 per hour and fraction thereof per representative for inspection work; $88.15 per hour or fraction thereof per representative for analytical or review work; $0.485 per mile for travel expenses by automobile; the government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day, per representative for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

19. In the event that, after the Effective Date, Eli Lilly establishes or acquires new business units or entities engaged in Promotional and Product Services Related Functions for Evista in the United States, Eli Lilly shall notify the Government of this fact as soon as possible, but no later than twenty (20) days prior to the date of the establishment or acquisition. This notification shall include the name and address of the new business unit or entity, its phone and

fax number. Each new business unit or entity shall be subject to this Decree.

20. Eli Lilly shall serve a copy of this Decree on any prospective purchaser of Eli Lilly or assignee at least thirty (30) days prior to such an assignment or change in ownership. Eli Lilly shall furnish the Government with an affidavit of compliance with this Paragraph sworn to by Eli Lilly's Chief Executive Officer no later than fifteen (15) business days prior to such assignment or change in ownership.

21. Eli Lilly shall notify the Government in writing at least fifteen (15) business days before any of the following events, if the event may affect the manner in which Eli Lilly complies with the obligations arising out of this Decree:

a. reorganization, bankruptcy, dissolution, or assignment or sale resulting in the emergence of a successor;

b. the creation of subsidiaries; or

c. any other material change of the corporate structure.

22. This Decree shall be binding on any successor, assigns, and transferees of Eli Lilly.

23. If Eli Lilly violates this Decree and is found in civil or criminal contempt thereof, Eli Lilly shall, in addition to other remedies, reimburse Plaintiff for its attorney's fees (including overhead), investigational expenses, expert witness fees, and court costs relating to such contempt proceedings.

24. Eli Lilly's obligations under this Decree do not modify or absolve Eli Lilly from any prospective obligation to comply with FDA Requirements, Federal Heath Care Program Requirements, or any other federal statute or regulation. Nothing in this Decree shall affect

FDA's authority to suspend or revoke any of Eli Lilly's applications pursuant to 21 U.S.C. § 355(e) or take any other action authorized by the FDCA or FDA regulations.

25. All communications required to be sent by Eli Lilly to the Government under this Decree shall be prominently marked "Decree Correspondence." Communications from Eli Lilly to the Government shall be sent to:

U.S. Department of Justice
Director, Office of Consumer Litigation
National Place Building, Room 950 N
1331 Pennsylvania Ave., N.W.
Washington, D.C. 20004-1710

All communications required to be sent by the Government to Eli Lilly under this Decree shall be prominently marked "Decree Correspondence" and shall be sent to:

Chief Compliance Officer
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

A copy shall be sent to:

Paul Kalb
Counsel for Eli Lilly and Company
Sidley Austin Brown & Wood LLP
1501 K Street, N.W.
Washington, D.C. 20005

All notifications and reports required by this Decree shall be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

26. This Decree does not in any way limit any administrative, civil, or criminal action that may be deemed appropriate to be taken by any agency or department of the United States,

except as provided for in the Plea Agreement between Eli Lilly, and the United States Attorney's Office for the Southern District of Indiana and the Office of Consumer Litigation of the Department of Justice, executed contemporaneously herewith.

27. A breach of this Decree does not constitute a breach of the Plea Agreement between Eli Lilly, and the United States Attorney's Office for the Southern District of Indiana and the Office of Consumer Litigation of the Department of Justice, executed contemporaneously herewith.

28. If Eli Lilly's agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Plea Agreement described in Paragraph 26 is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, the agreement to enter this Decree shall be null and void at the option of either the United States or Eli Lilly. If either the United States or Eli Lilly exercises this option, which option shall be exercised by notifying the other Party, through counsel, in writing within three (3) business days of the Court's decision, the other Party will not object and the agreement to enter this Decree will be rescinded. If this agreement is rescinded, Eli Lilly will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any such civil or administrative claims, actions or proceedings which are brought by the United States within ninety (90) calendar days of notification to the other Party of that rescission, except to the extent that the statute of limitations would have been a defense pursuant to the terms of a Tolling Agreement between the parties dated June 15, 2004, all subsequent extensions of that Tolling Agreement, and this Paragraph.

29. All decisions conferred upon FDA in this Decree shall be vested in the sole

discretion of FDA. Eli Lilly shall abide by the decisions of FDA, and FDA's decision shall be final. FDA's decisions under this Decree shall be reviewed by this Court under the standard set forth in 5 U.S.C. § 706(2)(A) ("arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."). Any matter brought before this Court shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

30. Any modifications to this Decree shall be made only with the prior written consent of the parties to this Decree and the approval by this Court.

31. The undersigned Eli Lilly signatory represents and warrants that he is fully authorized to execute this Decree on behalf of Eli Lilly and that the Board of Directors has approved entry into this Decree.

32. If, during any five year period after the Implementation Date of this Decree, the Government has not notified Eli Lilly that there has been a significant violation of this Decree during such five (5) year period, Eli Lilly may petition the Court to dissolve this Decree, and the Government will not oppose the petition.

33. This Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary and appropriate.

Dated this __ day of _____, ____.

UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of this Decree:

FOR DEFENDANT:

ROBERT ARMITAGE
Senior Vice President and General Counsel
on behalf of Eli Lilly and Company

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DATED: December 21, 2005

Attachment A to
Consent Decree of Permanent Injunction

IRO/CAS Engagements

1. IRO/CAS Engagement – General Description

Eli Lilly shall retain an independent entity (or entities) (hereinafter, "Independent Review Organization" or "IRO") to conduct reviews to assist Eli Lilly in assessing and evaluating Eli Lilly's systems, processes, policies, and procedures relating to the Promotional and Product Services Related Functions for Evista, and Eli Lilly's compliance with this Decree (the "Engagements").

Except as provided for in Paragraph 6.e(ii)(1) of the Decree, Eli Lilly shall retain an IRO to perform two types of Engagements: a Systems Engagement and a Transactions Engagement. For purposes of the Engagements, the Engagement Period for the First Reporting Period shall be the period from the Implementation Date through the first anniversary of the Effective Date. The Engagement Period for the Second Reporting Period through the Fifth Reporting Period shall be each respective corresponding Reporting Period (*i.e.*, the period from the relevant anniversary of the Effective Date through the subsequent anniversary).

Eli Lilly may engage a single IRO to perform both the Systems Engagement and the Transactions Engagement, provided that the IRO has the expertise and capabilities to perform both.

The Systems Engagement shall be performed for the periods covering the First and Fourth Reporting Periods, provided there are no material changes in Eli Lilly's systems, processes, policies, or procedures relating to the selling, detailing, marketing, advertising, promotion, or branding of Evista, or the dissemination of information about Evista. If Eli Lilly materially changes such systems, processes, policies, or procedures, the IRO shall perform a Systems Engagement for the Reporting Period in which such changes were made in addition to conducting the Systems Engagement for the First and Fourth Reporting Periods.

The Transactions Engagement shall be performed on an annual basis for the First through Fifth Reporting Periods.

After an IRO performs the Transactions Engagement for the first three Reporting Periods of the Decree, Eli Lilly may request the Government to permit the Transactions Engagement to be conducted by Eli Lilly's Corporate Audit Services ("CAS") subject to verification by an IRO. The Government retains sole discretion over whether to permit the Transactions Engagement to be conducted by the CAS. In making its decision, the Government will consider, among other factors, the results of the Transactions Engagement for the first three Reporting Periods and Eli Lilly's demonstrated audit

capabilities to perform the Transactions Engagement internally. If the Government denies Eli Lilly's request to shift the Transactions Engagement responsibilities to CAS, Eli Lilly agrees to engage an IRO to perform the remaining Transactions Engagements. Any Transactions Engagement conducted by CAS will be subject to verification by an IRO.

For each Engagement, the IRO (or CAS, as provided for in the Decree) shall prepare a written report (or reports). For each verification by an IRO, the IRO shall prepare a written report (or reports).

For each Engagement, the IRO (or CAS, as provided for in the Decree) may interview Eli Lilly personnel involved in the activities which are the subject of the Engagement.

2. **Systems Engagement**

For at least the First and Fourth Reporting Periods, the IRO shall review Eli Lilly's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions for Evista (as defined in the Decree). The IRO shall review Eli Lilly's systems, processes, policies, and procedures associated with the following:

a. Eli Lilly's systems, processes, policies, and procedures applicable to sales personnel who promote Evista in connection with their handling of requests or inquiries they may receive relating to off-label uses of Evista and in connection with their dissemination of information, if any, relating to off-label uses ("off-label use" includes any use other than those uses identified in the "Indications and Usage" section of the approved product label);

b. Eli Lilly's systems, processes, policies, and procedures through which requests and inquiries from health care providers ("HCP", which includes nurse practitioners within the definition of HCP) and/or sales personnel who promote Evista relating to how off-label uses of Evista are to be handled by Medical Information Systems (including a review of the manner in which Medical Information Systems receives and responds to such requests, the form and content of information disseminated by Medical Information Services, and the internal review process for the information disseminated).

c. Eli Lilly's systems, processes, policies, and procedures relating to consulting arrangements or any other contracts by Eli Lilly, entered with HCPs, and associated with Evista. This includes, but is not limited to, consulting arrangements or contracts with HCPs associated with meetings to obtain healthcare professional input or feedback, speaker training meetings, Advisors and Advisory Board meetings, Consultant Task Force meetings, Market Research meetings, and preceptor meetings. The IRO shall review:

i. the criteria used to determine whether, how many, and under what circumstances and venue such contracts will be entered and performed;

ii. the processes and criteria used to identify and select which HCPs with whom Eli Lilly enters consultant or other contractual arrangements;

iii. Eli Lilly's tracking or monitoring of services provided or the work performed by the consultants or other contractors (including the receipt of the consultant's or contractor's work product, if any);

iv. the uses made of work product received from consultants or other contractors, if any;

v. Eli Lilly's processes for establishing the rates paid to HCPs and the reasons or justifications for any differentials in the amounts paid to different HCPs;

vi. whether and in what manner Eli Lilly tracks or monitors the prescribing habits or product use of individuals or entities with whom it enters consulting or other contractual arrangements, if any;

vii. the budget funding source within Eli Lilly *(e.g.*, department or division) for the consulting or contractual arrangement; and

viii. the processes for insuring that any such consulting relationship or contract is reviewed for compliance with this Decree, FDA requirements, and Federal Health Care Program Requirements.

d. Eli Lilly's systems, processes, policies, and procedures relating to continuing medical education ("CME") and independent scientific exchange ("ISE"). This shall include:

i. The processes and procedures for referring all requests for support around CME and ISE activities to the Eli Lilly Grants Office ("LGO"); and

ii. Eli Lilly's policies and procedures, including approval requirements, relating to the standards and requirements that the LGO must follow with regards to the funding of CME and ISE activities.

e. Eli Lilly's systems, processes, policies, and procedures relating to speaker programs and peer-to-peer programs. This shall include:

i. The processes and procedures for the selection, administration, and training of speakers in the Lilly Lecture Bureau ("LLB");

ii. The processes and procedures for both the approval and dissemination of promotional and educational materials utilized in connection with a speaker program or peer-to-peer programs;

iii. The policies, processes and procedures related to the selection of program venue, meals, and entertainment in conjunction with speaker training events and subsequent speaker programs or peer-to-peer programs; and

iv. The policies, processes, procedures and systems related to the monitoring and control of speaker utilization and honoraria including but not limited to utilization, funding source, and any educational and practice related items ("EPRI" or "gifts").

f. Eli Lilly's systems, processes, and procedures relating to its system for approving the annual marketing plan for Evista, and approving, spending and monitoring funds by the Evista Brand Team and Eli Lilly's United States Market Research relating to Evista;

g. Eli Lilly's systems, processes, policies, and procedures relating to the disciplinary actions that Eli Lilly may impose in the event a Covered Person violates this Decree, the Red Book, or Eli Lilly's Policies and Procedures;

h. Eli Lilly's criteria or plans for compensating (including with salaries and bonuses) members of the Evista Brand Team, and members of any sales force responsible for marketing, detailing or selling Evista. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance.

3. **Systems Engagement Report**

Following each Systems Engagement, the IRO shall prepare a report based upon its review. For each set of systems, processes, policies, and procedures identified in Section 2(a)-(g) above, the report shall include the following items:

a. a description of the documentation reviewed and any personnel interviewed;

b. a detailed description of Eli Lilly's systems, processes, policies, and procedures with regard to the items identified in Section 2(a)-(g) above, including a general description of Eli Lilly's control and accountability systems (e.g., documentation and approval requirements, tracking mechanisms) and written policies regarding the systems, processes, policies, and procedures reviewed;

c. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections 2(a)-(g) above are made known or disseminated within Eli Lilly;

d. a detailed description of Eli Lilly's compensation system (including salaries and bonuses) for members of the Evista Brand Team, and members of any sales force responsible for marketing, detailing or selling Evista, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance.

e. findings and supporting rationale regarding any weaknesses in Eli Lilly's systems, processes, policies, and procedures reviewed, if any; and

f. recommendations to improve any of the systems, processes, policies, and procedures reviewed, if any.

Prior to the submission of the IRO's report to the Government, Eli Lilly shall be provided with a copy of the report and an opportunity to respond to each comment made by the IRO. Provided it does not delay the timely filing of the Annual Report, any responses by Eli Lilly may be included in the IRO report submitted to the Government. Otherwise, any responses by Eli Lilly to the IRO's findings may be submitted to the Government following the Annual Report submission.

4. **Transactions Engagement**

For the First through Fifth Reporting Periods, the IRO (or CAS, as provided for in the Decree) shall conduct a Transactions Engagement relating to Promotional and Product Services Related Functions for Evista.[1] The Transactions Engagement shall include the review of: documents relating to monitoring activities of Eli Lilly's Compliance Office; approval forms for obtaining Healthcare Professional input/feedback; and documents relating to investigation of claims received by the Compliance and Ethics Helpline and the Chief Compliance Officer ("CCO").

a. Background on CCO's Monitoring Records

Prior to the Effective Date, Eli Lilly voluntarily implemented policies and procedures that its Compliance Office utilizes to help the company ensure compliance with its Good Promotional Practices ("GPPs") and Compliance Policies and Procedures ("CPPs"). The Compliance Office has developed protocols and monitoring forms for the activities identified in the following chart. The Compliance Office assigns a rating (Green, Yellow, or Red) for each activity that is monitored.

For purposes of Paragraph 4.a, "Control Documents" include the documents identified in the following chart:

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[1] If CAS conducts the Transactions Engagement, all references to the IRO in Paragraphs 4 and 5 of this Attachment A should be interpreted to mean CAS.

Protocol	Monitoring Form	Required Forms if Activity Rated Yellow or Red
Protocol for Monitoring Global Medical Conference (Includes IMC, RMC, and Individual Country Programs)	Global Medical Conference (Includes IMC, RMC, and Individual Country Program) Monitoring Checklist	Compliance Corrective Action Form
Protocol for Monitoring US/Global Advisory Board or Consultant Task Force Activity/Meeting	US/Global Advisory Board or Consultant Task Force Meeting Monitoring Checklist	Compliance Corrective Action Form
Protocol for Monitoring FDA Regulated Speaker Training	FDA Regulated Speaker Training Monitoring Checklist	Compliance Corrective Action Form
Protocol for Monitoring an FDA Regulated Speaker Program	FDA Regulated Speaker Program Monitoring Checklist	Compliance Corrective Action Form
Protocol for Exhibit Monitoring	Exhibit (Includes Promotional, Disease State, International, Medical/Scientific, and Market Research) Monitoring Checklist	Compliance Corrective Action Form
Protocol for District Good Business Practice Reviews	Checklist of GBP Report (Pre-Work); Good Business Practice Review DM Guide; and Good Business Practice Review Action Plan and Executive Summary	Compliance Corrective Action Form
Protocol and Checklist for Representative Ride Alongs	Rep Ride Along Checklist	Compliance Corrective Action Form
ID School & Sales Meeting Monitoring Protocol	ID School & Sales Meeting Monitoring Checklist	Compliance Corrective Action Form

i. Selection of Monitoring Records for Review

The IRO shall obtain from Eli Lilly a list of all activities that include

Promotional and Product Services Related Functions for Evista that were monitored by the Compliance Office during the relevant Reporting Period.[2] For each activity, the IRO shall review the Control Documents.

ii. Identification of Material Errors and Additional Review

(1) The IRO will find there to be a Material Error in connection with the Control Documents and shall note such Material Errors if a Control Document does not exist for an activity and through follow-up the IRO is unable to determine that Eli Lilly otherwise followed its protocols.

(2) The IRO will find there to be a Material Error in connection with the Control Documents and shall note such Material Errors if a Compliance Corrective Action Form or Compliance Monitoring Follow-up Form does not exist for an activity that was rated Yellow or Red.

(3) If a Control Document does not exist or is misplaced but the IRO can otherwise determine the protocol was followed, the IRO shall not consider this to be a Material Error, but rather an exception and it shall be reported as such.

(4) If the IRO finds any Material Errors, it shall conduct additional review to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation or conduct interviews with appropriate personnel to identify the root cause of the errors.

b. Background on Approval Forms for Obtaining Healthcare Professional Input/Feedback

Prior to the Effective Date, Eli Lilly voluntarily implemented Compliance Policies and Procedures – Marketing, Obtaining HCP Professional Input/Feedback (use of Advisors/Consultants/Market Research) (MAR-NP-CPP 02-006). These policies and procedures require that the Evista Brand Team Manager or B2B Manager must provide written justification for all communications with HCP advisors consistent with the HCP's role. The Manager must complete Attachment 1 to CPP 02-006, HCP Advisory Board

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[2] Consistent with existing practice, Eli Lilly's Compliance Office will monitor a minimum of 60 activities related to Evista during each Reporting Period. This will include a minimum of 20 ride alongs with sales representatives for Evista and 10 speaker programs for Evista.

Activity/Communication Approval Form. These policies and procedures also require, with respect to feedback activities, that after the Market Research department determines the need for a Consultant Task Force meeting, the Evista Brand Team Manager proposing the feedback activity must complete an Approval Form indicating: the specific purpose of the program or activity (in sufficient detail to distinguish the purpose of this program or activity from other programs or activities); the proposed number of consultants; justification for the number of consultants consistent with the purpose; selection criteria for consultants consistent with the purpose; a list of potential consultants to be used; work product to result from the program; and use of the work product. The Approval Form must be signed off by the Brand Team Leader, the Business Unit Leader or Group Brand Marketing Leader, and the appropriate Director of Market Research. This Form is identified as Attachment 2 to CPP 02-006, HCP Consultant Task Force Meeting Approval Form.

For purposes of Paragraph 4.b, "Control Documents" include Attachment 1 to CPP 02-006, HCP Advisory Board Activity/Communication Approval Form, and Attachment 2 to CPP 02-006, HCP Consultant Task Force Meeting Approval Form.

i. Selection of Approval Forms for Review

The IRO shall obtain from Eli Lilly a list of all activities related to Evista and soliciting HCP Input/Feedback during the relevant Reporting Period. For each activity, the IRO shall review the Control Documents.

ii. Identification of Material Errors and Additional Review

(1) The IRO will find there to be a Material Error in connection with the Control Documents and shall note such Material Errors if a Control Document does not exist for an activity and through follow-up the IRO is unable to determine that Eli Lilly otherwise followed CPP 02-006.

(2) The IRO will find there to be a Material Error in connection with the Control Documents and shall note such Material Errors if a review of the Control Documents indicates that CPP 02-006 was not followed.

(3) If a Control Document does not exist or is misplaced but the IRO can otherwise determine that CPP 02-006 was followed, the IRO shall not consider this to be a Material Error, but rather an exception and it shall be reported as such.

(4) If the IRO finds any Material Errors, it shall conduct additional

review to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation or conduct interviews with appropriate personnel to identify the root cause of the errors.

c. Background on Documents relating to the Compliance and Ethics Helpline

Prior to the Effective Date, Eli Lilly voluntarily implemented a policy that Eli Lilly employees are required to report any possible violations of the law, Red Book, or company policies to their supervisor, human resource representatives, company attorney, the CCO or the Compliance and Ethics Helpline. Eli Lilly has established procedures to address handling of reports made to both the CCO and the Compliance and Ethics Helpline regarding potential or actual violations of the law, the Red Book, or company policies ("Procedures for Investigation of Claims Received by the Compliance and Ethics Helpline and the CCO, hereinafter referred to as "Hotline Procedures"). The Compliance and Ethics Helpline is operated for Eli Lilly by a third party administrator. Calls to the Compliance and Ethics Helpline, other than those that require immediate action due to a report of actual harm or allegation of immediate threat to person, property or environment, are referred to Eli Lilly's CCO by the next business day following receipt of the call by the Compliance and Ethics Helpline. A referral report of the facts obtained during the call is provided.

The CCO refers all such calls for investigation within two business days of receipt of the report from the third party administrator. When referring a claim the CCO includes the following materials: claim summary provided by the third party administrator or if the claim was received directly by the CCO, a summary of the telephone conversation or the actual written complaint; Investigation Referral Form that describes the guidelines regarding: the involvement of Line Human Resource personnel at the outset of the investigation and before contemplating any disciplinary action, the importance of complying with policies on confidentiality and non-retaliation, and the timing for conducting the investigation; Investigative Report Form to be returned to the CCO with the results of the investigation so that the completion of the investigation can be tracked.

As part of each investigation, completed forms as set forth in Attachments C, D, E, F, and G of the Hotline Procedures are created and maintained by the CCO.

The CCO prepares a quarterly report for the Chief Executive Officer and the Public Policy and Compliance Committee in joint session with the Audit Committee of the Board of Directors regarding investigated claims. Such report includes: Number of calls or claims received through the Compliance and Ethics Helpline or by direct contact with the CCO; Types of claims received; Any actions taken (i.e., additional training implemented, disciplinary actions

considered and taken); and Serious violations (along with remedial action taken). A sample of this quarterly report is attached as Attachment H to the Hotline Procedures.

For purposes of Paragraph 4.c, "Control Documents" include completed forms as set forth in Attachments C, D, E, F, and G of the Hotline Procedures for each call or claim, and the quarterly reports set forth in Attachment H of the Hotline Procedures.

i. Selection of Documents relating to the Compliance and Ethics Helpline for Review

The IRO shall obtain from Eli Lilly a list of all calls or claims to the Compliance and Ethics Helpline that involve Evista during the Reporting Period. For each call or claim, the IRO shall review the Control Documents.

ii. Identification of Material Errors and Additional Review

(1) The IRO will find there to be a Material Error in connection with the Control Documents and shall note such Material Errors if a Control Document does not exist for a call or claim and through follow-up the IRO is unable to determine that Eli Lilly otherwise followed the Hotline Procedures.

(2) The IRO will find there to be a Material Error in connection with the Control Documents and shall note such Material Errors if a review of the Control Documents indicates that the Hotline Procedures were not followed.

(3) If a Control Document does not exist or is misplaced but Eli Lilly has taken corrective action prior to the IRO review, or the IRO can otherwise determine that the Hotline Procedures were followed, the IRO shall not consider this to be a Material Error, but rather an exception and it shall be reported as such.

(4) If the IRO finds any Material Errors, it shall conduct additional review to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation or conduct interviews with appropriate personnel to identify the root cause of the errors.

5. **Transactions Engagement Report**

For each Reporting Period, the IRO shall prepare a report based on its Transactions

Engagement. The report shall include the following:

a. Elements to be included:

   i. Transactions Engagement Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

   ii. Engagement Protocol: A detailed narrative description of the procedures performed; and

   iii. Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Transactions Engagement.

b. Results to be included:

   i. the IRO shall state its findings and supporting rationale as to whether: (1) all required documentation exist; (2) each document was complete and maintained in accordance with all requirements set forth in the applicable Eli Lilly policy; (3) each document reflects that Eli Lilly's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (4) any disciplinary action was taken in those instances in which an Eli Lilly policy was not followed;

   ii. for each document reviewed; the IRO shall identify all exceptions discovered. For the exceptions, the IRO shall describe in general terms what the errors were. The IRO shall describe those situations where corrective action was taken prior to the IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action;

   iii. for each document reviewed, the IRO shall identify any Material Errors that were discovered. For the Material Error, the IRO shall describe the Material Error in detail and shall describe the additional review procedures it performed. The IRO shall state its findings as to the root cause of each Material Error(s); and

   iv. the IRO's recommendations, if any, for changes in Eli Lilly's systems, processes, policies, and procedures, in order to correct or address any weaknesses or deficiencies uncovered during the Transactions Engagement. The IRO shall provide findings and supporting rationale for any such recommendations.

6. **IRO Verification of CAS Transactions Engagement**

a. If CAS conducts a Transactions Engagement, the IRO shall conduct a Verification Testing Engagement of at least 20% of transactions reviewed by CAS. The IRO will independently obtain source control documentation relating to the transactions under review by CAS and will independently conduct the steps outlined in Section 4 above. After the IRO has conducted its verification testing engagement it shall: (1) obtain CAS's findings with regards to each of the transactions reviewed; (2) compare its findings to those of CAS; (3) identify any discrepancies between the two sets of findings; and (4) explain potential reasons for the discrepancies.

b. If the IRO identifies errors in any of CAS's findings, the IRO shall conduct additional verification testing of the entire population of transactions reviewed by CAS. If the IRO identifies any Eli Lilly errors in this additional engagement, Eli Lilly and the IRO shall notify the Government to discuss appropriate additional steps to be taken (e.g., additional reviews or a requirement that an IRO, rather than CAS, conduct all or part of future Engagements).

c. The IRO shall prepare a report based upon its Engagement ("IRO Verification Report"). The IRO Verification Report shall contain, for each transaction: (1) the IRO's findings; (2) a detailed description of any discrepancies between the IRO's findings and those of CAS; and (3) the IRO's explanation of the possible reasons for those discrepancies. In addition, if the IRO conducted any additional verification review(s) (beyond the 20% initial review), the IRO Verification Report shall contain a detailed description of the results of that review, including the IRO's findings. The IRO Verification Report shall be provided to the Government pursuant to the Consent Decree.